K132980

JAN - 8 2014

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Section 5 510(k) SUMMARY Traditional 510K

Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201 Fax: (215) 256-9191
Contact:	Timothy Holwick Regulatory Associate
Date Prepared:	September 12, 2013
Trade Name:	Medcomp® Power Injectable Safety Huber Needle
Common Name:	Intravascular Administration Set
Classification Name:	Subcutaneous, implanted, intravascular infusion port and catheter
Classification Panel:	General Hospital
C.F.R. Sections	§880.5440
Product Code:	FPA
Class:	II
Predicate Devices:	K080544, CT Injectable Safety Huber Needle, concurrence date August 14, 2008.

Device Description:

The Power Injectable Safety Huber Needle is composed of a sharpened anti-coring Huber style needle for port septum access having a safety feature which is manually operated and will prevent accidental needle sticks when advanced which is connected to a conventional style extension set for attachment to standard IV/Drug infusion line sets.

The proximal end of the needle cannula is adhesively sealed to the molded housing which contains a glue well and fluid thru hole. The fluid thru hole leads to the distal end of the extension line set that is also adhesively bonded in the molded housing. The distal end of the extension tubing contains a female luer connector with removable dust cap on the proximal end creating a fluid path from the needle tip thru the female luer. The infusion set is also offered in a configuration where the extension tubing contains a Y-Site connector with removable dust cap placed midway between the needle and the female luer connector. The extension tubing contains purple pigment to indicate its use for high pressure. The Y portion of the connector is a molded female luer that is sealed with a removable dust cap. A non-removable pinch clamp is located between the female luer and needle cannula. On line sets with a Y-Site connector, two pinch clamps are present located between the female luer and the Y-Site and the Y-Site and the needle cannula. The pinch clamps are designed that when engaged, fluid flow is restricted thru the extension tubing.

The needle cannula is constructed with a Huber style anti-coring needle tip. The cannula is stainless steel and is shielded by a removable star needle guard of plastic construction.

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The molded wing housing is of plastic construction and contains rigid protruding wings.

The molded wing housing is snap fitted into the molded housing via a securement post. The wing housing is of plastic construction with a protruding wing designed flush with the under surface of the housing. The wing housing contains a thru hole that easily slides over the needle cannula. The wing housing contains a torsion spring that is positioned on a post and is orientated in a positioning channel. The torsion spring is in a compressed state until the molded housing is removed from the wing housing at which time the torsion spring is automatically activated. The wing housing consists of a base to which the securement bag is adhesively bonded.

The molded housing is connected to the wing housing via the securement bag. The securement bag (a polyester film lamination) is adhesively bonded to the molded housing and the wing housing. The securement bag is compressed (accordion style) between the molded housing and wing housing and is of length sufficient to activate the torsion spring and to prevent the needle tip from entering the securement bag area.

In normal operation, the molded housing is activated during removal of the needle from the patient. The wing housing is held firmly in place while the molded housing is disengaged. The molded housing is disengaged from the wing housing by grasping the elevated portion of the molded housing and sliding the molded housing in an upward direction. The molded housing will disengage from the wing housing and will advance until the torsion spring is past the needle tip at which time the torsion spring will snap over the needle access hole. Upon spring activation, there will be an audible click sound as the spring snaps against the wing housing. The securement bag prevents the molded housing from advancing off the needle cannula and the torsion spring prevents the needle from advancing out of the housing.

Prior to use, the exposed portion of the needle cannula, including the sharpened needle tip area, is coated with a silicone fluid to render the needle lubricious and to reduce the insertion (penetration) and drag force to industry acceptable values.

Each needle size has I.D. Rings located within the pinch clamp to identify the appropriate infusion rate for the noted needle gauge size. Components will be assembled by the manufacturer into standard configurations with or without the "Y-Site" and packaged.

Indications for Use:

The Medcomp® Power Injectable Huber Needle Safety Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through implanted vascular access ports. The Medcomp® Power Injectable Huber Needle Safety Infusion Set is also indicated for power injection of contrast media into the central venous system with implanted vascular access ports indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 ml/sec for 19 gauge and 20 gauge non-coring Huber style needles and 2 ml/sec for 22 gauge non-coring Huber style needles.

Comparison to Predicate Devices:

The power Injectable safety Huber needle is substantially equivalent to the predicate device in terms of intended use, basic design, materials, performance, labeling, manufacturing process and method of sterilization.

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Bench / Performance Data:

Pressure testing has been performed on each needle gauge size to determine pressure ratings. Pressure ratings for the appropriate needle gauge is located on the I.D. Ring located within the infusion line clamp.

Clinical studies were not deemed necessary since no changes have been made to the design, packaging, sterilization or indications for use that would have any effect on the safety and effectiveness of the device when compared to the legally marketed predicate device.

Biocompatibility:

Testing for all materials is found in Section 15. All biocompatibility testing demonstrates the materials used meet the requirements of ISO 10993.

Technological Characteristics:

Technological similarities between the proposed devices and predicate devices remain the same.

Summary of Substantial Equivalence:

The proposed devices meet the performance criteria of design verification as specified by ISO standards, guidance documents and internal test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 8, 2014

MEDCOMP®
Mr. Timothy Holwick
Regulatory Associate
1499 Delp Drive
Harleysville, PA 19438

Re: K132880
Trade/Device Name: Medcomp® Power Injectable Safety Huber Needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 20, 2013
Received: September 23, 2013

Dear Mr. Holwick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132880

Device Name
Medcomp® Power Injectable Safety Huber Needle

Indications for Use *(Describe)*

The Medcomp® Power Injectable Huber Needle Safety Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through implanted vascular access ports. The Medcomp® Power Injectable Huber Needle Safety Infusion Set is also indicated for power injection of contrast media into the central venous system with implanted vascular access ports indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 ml/sec for 19 gauge and 20 gauge non-coring Huber style needles and 2 ml/sec for 22 gauge non-coring Huber style needles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.01.06 08:05:47 -05'00'

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